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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/419,611	10/18/1999	HIROSHI IZUI	0010-1045-0	1525

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EXAMINER

TUNG, PETER P

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 12/04/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/419,611

Applicant(s)

Izui et al.

Examiner

Peter Tung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 13, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, and 6-14 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, and 6-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other:

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DETAILED ACTION

1. Claims 1, 2 and 6-14 are pending.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 6, 8 and 10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an enterobacteria containing DNA encoding *Brevibacterium lactofermentum* citrate synthase, does not reasonably provide enablement for an enterobacteria containing DNA encoding any coryneform bacterial citrate synthase. This rejection is explained in the previous Office action.

4. Applicants argue that coupled with the standard knowledge available in the art (as illustrated by the cited instant reference) the present specification clearly enables the skilled artisan to make and/or use the invention. The instant reference teaches the *Corynebacterium glutamicum* *gltA* gene which encodes citrate synthase. The instant reference further teaches the amino acid sequence of several other bacterial citrate synthases and that these amino acid sequences have highly conserved regions. Applicants argue that therefore coryneform bacterial citrate synthase genes other than the *Brevibacterium lactofermentum* gene can be cloned by conventional methods.

5. Applicant's arguments filed 7/13/01 have been fully considered but they are not persuasive. While other bacterial citrate synthases are known, the prior art does not appear to teach any other

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coryneform bacterial citrate synthases besides *Corynebacterium glutamicum* and *Brevibacterium lactofermentum*. This is insufficient to enable the scope claimed of coryneform bacterial citrate synthase genes.

6. Claim 1, 6, 8 and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims are drawn to an enterobacteria containing a citrate synthase gene derived from a coryneform bacterium. However, the instant disclosure only teaches enterobacteria containing *Brevibacterium lactofermentum* citrate synthase DNA. The specification and claims do not indicate what distinguishing attributes are shared by the members of the claimed genus of enterobacteria containing a citrate synthase gene derived from a coryneform bacterium. The scope of the claim includes numerous chemical species with widely differing structural, chemical and physical characteristics and the genus is highly variable because a significant number of structural differences between genus members is permitted. The specification and the claims do not provide any guidance as to what is essential to the operation and function of the claimed enterobacteria containing a citrate synthase gene derived from a coryneform bacterium and what characteristics could distinguish bacteria in the genus from others in the genus are missing from the disclosure. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variable, the disclosure of enterobacteria containing *Brevibacterium lactofermentum* citrate

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synthase DNA is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus of an enterobacteria containing a citrate synthase gene derived from a coryneform bacterium. *see University of California v. Eli Lilly and Co. 43 USPQ2d 1398.*

7. Claims 1, 2 and 6-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is explained in the previous Office action.

8. Applicants argue that the present application provides a clear description of the source of the citrate synthase gene, methods of isolating the gene and methods of introducing the gene into a bacteria. Applicants argue that a skilled artisan would understand the conserved regions of citrate synthase as disclosed in the submitted reference and use this information with the instant disclosure. Applicants conclude that the specification thus provides the skilled artisan a clear indication that the inventors had possession of the claimed invention at the time the application was filed.

9. Applicant's arguments filed 7/13/01 have been fully considered but they are not persuasive. While the source and methods involving DNA encoding citrate synthase are described both in the instant application and in the instant reference, a citrate synthase gene is still not disclosed. As stated in the previous Office action, adequate description of the structure of the citrate synthase gene would include more than just the coding sequence of a protein but would also include the

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regulatory, promoter and terminator sequences that precede and follow the coding sequence. It is noted that this rejection may be overcome by replacing "gene" with "DNA."

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1, 2 and 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katsumata et al. (cited in IDS). Katsumata et al. teach (abstract) microorganisms containing DNA encoding corynebacterium citrate synthase. Katsumata et al. teach that these microorganisms are used to produce glutamic acid. Katsumata et al. do not teach *Klebsiella planticola* or *Enterobacter agglomerans* transformed with DNA encoding corynebacterium citrate synthase.

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Klebsiella planticola and *Enterobacter agglomerans* are known by those of ordinary skill in the art. The prior art does not teach *Klebsiella planticola* or *Enterobacter agglomerans* containing DNA encoding corynebacterium citrate synthase. *Klebsiella planticola* or *Enterobacter agglomerans* comprising DNA encoding corynebacterium citrate synthase would have been obvious to one of ordinary skill in the art at the time the invention was made for the benefit of a microorganism containing DNA encoding an enzyme of interest. As the two bacteria are known in the art to be transformable with DNA, the bacteria can serve to propagate DNA encoding corynebacterium citrate synthase. One of ordinary skill in the art would have a reasonable expectation of success at doing this as transformation of the bacteria is well known in the art. Therefore the invention as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

Allowable Subject Matter

12. Claims 10-14 are allowable over the prior art of record. The prior art of record does not teach or suggest a method of producing L-glutamic acid by culturing the claimed enterobacteria which contain DNA encoding corynebacterium citrate synthase.


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Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Tung, Ph.D. whose telephone number is (703) 308-9436. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D., can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


NASHAAT T. NASHED PHD.
PRIMARY EXAMINER